Advisory Action	Application No.	Applicant(s)	
	09/445,480	JONGSMA ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

--The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 14 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *14 August 2003*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☒ The proposed amendment(s) will not be entered because:

(a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: *See Continuation Sheet*.

3.☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: *27*.

Claim(s) objected to: _____.

Claim(s) rejected: *8,10-14,17,18,24 and 28-39*.

Claim(s) withdrawn from consideration: *1-7, 19-23 and 25-26*.

8.☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☒ Other: *See Continuation Sheet*

Continuation of 2. NOTE:
New issues:
112 2nd:
Claims 24 and 28-33 are indefinite in their recitation of "substantially similar of ... SEQ ID NO:2"; it is unclear how different in biological activity a protein can be and still be "substantially similar". It is also unclear which biological activity of SEQ ID NO:2 is being refered to.
Claim 10 lacks antecedent basis for the limitation " the thus formed reproduced plants" in lines 4-5.

Continuation of 3. Applicant's reply WOULD HAVE overcome the following rejection(s):
112, 1st over claim 16 (paragraph 10 of the Office action mailed 11 February 2003).
102(b) over claims 24, 28-33 and 37-39 as being anticipated by Walsh et al (WO 92/21753).

Continuation of 5. does NOT place the application in condition for allowance because:
112, 1st, written description, claims 8, 10-14, 17-18, 24 and 28-39: Applicant urges that the specification does describe the structural features of other cysteine inhibitors containing at least one type I repeated thyroglobulin domain, including SEQ ID NO:2, pg 18-19, and Fig. 2 (response pg 15-16). This is not found persuasive: The specification at pg 18, lines 33-34 states that a one type I repeated thyroglobulin domain "show[s] high conservation of the amino acid sequence ..." It is not clear what "high conservation" is - how different can a sequence be and still be a one type I repeated thyroglobulin domain? The specification also does not describe how to distinguish type I repeated thyroglobulin domain-containing proteins that are cysteine protease inhibitors from type I repeated thyroglobulin domain-containing proteins that are not cysteine protease inhibitors. The specification also does not describe the sequence of a representative number of proteins that have a biological activity that is "substantially similar" to that of SEQ ID NO:2 and that contain at least one type I repeated thyroglobulin domain.
112, 1st, enablement, claims 8, 10-14, 17-18, 24 and 28-39: Applicant urges that one skilled in the art should be able to isolate furtthe thyroglobulin genes based on reading the specification, for example by using the consensus sequence in Fig 2 to make degenerate oligonucleotides based on known codon sequences, and then using the primers in a variety of methods to isolate full-length genes (response pg 16-18). This is not found persuasive. The specification does not teach this isolation procedure. See Genentech, Inc. v. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a "mere germ of an idea does not constitut [an] enabling disclosure", and that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention. The specification also does not teach how to distinguish type I repeated thyroglobulin domain-containing proteins that are cysteine protease inhibitors from type I repeated thyroglobulin domain-containing proteins that are not cysteine protease inhibitors; in fact the specification teaches that those distinguishing features are not known (see pg 7, lines 18-20).
112, 1st, new matter, claims 37 and 39: Applicant did not point to support for the use in the instant method of the nucleic acids encoding human p41 invariant chain fragment or a protein isolated from the eggs of chum salmon.

Continuation of 10. Other:
Claims 30-21 were not "currently added" in the response filed 14 August 2003, but were amended.
Applicant did not amend the the Brief Description of the Drawings for Figures 1 and 2 as required under the sequence rules (See paragraph 8 of the Office action mailed 11 February 2003).
The amendments to the specification and the abstract were also not entered because 1) the amendments to the claims were not entered and 2) the amendments to the specification did not address all the sequence issues, as above.

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